Initial Approval Date: April 21, 2021

CRITERIA FOR PRIOR AUTHORIZATION

Chimeric Antigen Receptor T-Cell (CAR-T) Therapy Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available.
All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Axicabtagene ciloleucel (Yescarta®)
Brexucabtagene autoleucel (Tecartus®)
Idecabtagene vicleucel (Abecma®)
Lisocabtagene maraleucel (Breyanzi®)
Tisagenlecleucel (Kymriah®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, weight (if applicable), and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with an oncologist or hematologist. [1]
- For all agents listed, the preferred PDL drug, WHERE APPLICABLE, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Patient has not received previous CAR T-cell therapy.
- For all agents, patient must have relapsed or refractory (r/r) disease despite chemotherapy with at least 2 different agents, each with a different mechanism of action, unless otherwise specified below: [1,2,6-8]
    - For **tisagenlecleucel** in patients with Philadelphia chromosome positive (Ph+) B-cell precursor acute lymphoblastic leukemia (B-ALL), must meet the following:
        - Patient must have r/r disease despite treatment with 2 or more tyrosine kinase inhibitors (TKI). [1]
    - For **idecabtagene vicleucel**, must meet the following:
        - Patient must have r/r multiple myeloma despite treatment with 4 or more lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody.[3,10]

Table 1. FDA-approved age, indication, and dosing limits.[6-10]

Medication	Indication(s)	Age	Dosing Limits
Axicabtagene ciloleucel (Yescarta®)	Treatment of r/r large B-cell lymphoma (including DLBCL NOS, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma and DLBCL arising from FL) Treatment of r/r FL	≥ 18 years	2 x 10^6 CAR-positive viable T cells per kg body weight (or a maximum of 2 x 10^8 CAR-positive viable T cells for patients 100 kg and above)
Brexucabtagene autoleucel (Tecartus®)	Treatment of r/r MCL	≥ 18 years	2 x 10^6 CAR-positive viable T cells per kg body weight (maximum of 2 x 10^8 CAR-positive viable T cells for patients 100 kg and above)
Idecabtagene vicleucel (Abecma®)	Treatment of r/r multiple myeloma	≥ 18 years	300 to 460 x 10^6 CAR-positive T cells
Lisocabtagene maraleucel (Breyanzi®)	Treatment of r/r large B-cell lymphoma (including DLBCL NOS, high grade B-cell lymphoma, primary mediastinal large B-cell lymphoma and FL grade 3B)	≥ 18 years	50 to 110 x 10^6 CAR-positive viable T cells
Tisagenlecleucel (Kymriah®)	Treatment of r/r B-ALL	≤ 25 years	≤ 50 kg: 0.2 to 5.0 x 10^6 CAR-positive viable T cells per kg body weight > 50 kg: 0.1 to 2.5 x 10^8 total CAR-positive viable T cells
	Treatment of r/r large B-cell lymphoma (including DLBCL NOS, high grade B-cell lymphoma and DLBCL arising from FL)	≥ 18 years	0.6 to 6.0 x 10^8 CAR-positive viable T cells

r/r = relapsed or refractory; MCL = mantle cell lymphoma; CAR = chimeric antigen receptor; DLBCL = diffuse large B-cell lymphoma; NOS = not otherwise specified; FL = follicular lymphoma; B-ALL = B-cell precursor acute lymphoblastic leukemia

LENGTH OF APPROVAL: 3 months (1 infusion per lifetime). Reauthorization is not permitted.

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:
THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.

Notes:

Tecartus (brexucabtagene autoleucel)	This is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.[1] Additional follow-up to ZUMA-2 (NCT02601313) is expected after July 31, 2021. In the same ZUMA-2 study, another cohort will be added to ZUMA-2 to look at subjects with r/r MCL who have not been exposed to a BTK inhibitor. Results of this additional subgroup are expected after October 31, 2025.[4]
Yescarta (axicabtagene ciloleucel)	The follicular lymphoma indication is approved under accelerated approval based on response rate (ZUMA-5; NCT03105336). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[5,8]

References:

1. National Comprehensive Cancer Network (NCCN). Acute Lymphoblastic Leukemia. (Version 1.2021) April 6, 2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed on April 13, 2021.
2. National Comprehensive Cancer Network (NCCN). B-cell Lymphomas. (Version 3.2021) March 16, 2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on April 13, 2021.
3. National Comprehensive Cancer Network (NCCN). Multiple Myeloma. (Version 6.2021) April 12, 2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed on April 13, 2021.
4. U.S. Food and Drug Administration. July 23, 2020 Summary Basis for Regulatory Action – TECARTUS. Available at https://www.fda.gov/media/141093/download. Accessed April 14, 2021.
5. U.S. Food and Drug Administration. FDA grants accelerated approval to axicabtagene ciloleucel for relapsed or refractory follicular lymphoma. March 5, 2021. Available at: https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-axicabtagene-ciloleucel-relapsed-or-refractory-follicular-lymphoma. Accessed March 12, 2021.
6. Tecartus (brexucabtagene autoleucel) [prescribing information]. Santa Monica, CA: Kite Pharma, Inc.; February 2021.
7. Breyanzi (lisocabtagene maraleucel) [prescribing information]. Bothell, WA: Bristol-Myers Squibb; February 2021.
8. Yescarta (axicabtagene ciloleucel) [prescribing information]. Santa Monica, CA: Kite Pharma, Inc.; March 2021.
9. Kymriah (tisagenlecleucel) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2020.
10. Abecma (idecabtagene vicleucel) [prescribing information]. Summit, NJ: Bristol-Myers Squibb; March 2021.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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PHARMACY PROGRAM MANAGER
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